Plan B Timeline

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July 28, 1999 The U.S. Food and Drug Administration approves Plan B, an emergency contraceptive (EC) pill, for prescription use.

Feb. 14, 2001 Over 70 medical and public health organizations file a citizens' petition with the DA to make Plan B available over-the-counter (OTC).

April 21, 2003 Plan B's manufacturer files an application for OTC use with the FDA.

December 8, 2003 Representative Joseph Pitts, along with 43 Republican Members of Congress, including Majority Leader Tom Delay, send letter to FDA urging it to reject Plan B for OTC status.

Dec. 16, 2003 An Independent FDA panel of experts recommend Plan B for OTC status by a vote of 23 to 4. The panel makes a unanimous finding that Plan B is safe and effective.

January 30, 2004 Representative Maloney, along with 75 bipartisan Members of Congress send letter to then-Commissioner Mark McClellan expressing support for the recommendation of the expert panel to grant OTC to Plan B.

May 6, 2004 In a rare move overriding the recommendations of its professional staff, the FDA issues a "not approvable" letter to barr Laboratories and raises questions about Plan B's potential effect on young women's health and behavior to justify the denial.

May 17, 2004 Representative Maloney, along with 28 Members of Congress, send letter to the Government Accountability Office (GAO) requesting an investigation of FDA for its decision not to make emergency contraception available for OTC use.

May 17, 2004 Representative Maloney introduces the HR 4377, the Science Over Politics Act, which requires that 30 days after enactment of the legislation, the FDA Commissioner would have to review his prior decision on Plan B® and affirm 1) that his decision was not politically influenced, 2) that it was based on sound science, and 3) that it conformed to FDA precedent and procedures. He must affirm these items, under penalty of law.

July 13, 2004 Representatives Maloney and Waxman successfully offer and pass an amendment to HR 4766, the FY05 Agriculture Appropriations bill, that would require the FDA to do the job it is supposed to be doing - determining what is safe and effective contraception. The amendment

survives the conference committee and is included in HR 4818, the Omnibus Appropriations Conference Report of November 20, 2004.

July 22, 2004 Barr Laboratories submits a revised "dual label status" proposal that would make Plan B available without a prescription only to women aged 16 and older. Women 15 and younger would continue to need a prescription.

October 2004 Anthony Means, MS, PhD, President of the Endocrine Society sends letter to House and Senate members of the Agriculture Appropriations Subcommittee on behalf of its 11,000 members in support of Representative Maloney's Agriculture Appropriations amendment.

January 19, 2005 Representative Maloney joins 51 Members of Congress in sending letter to FDA Commissioner Lester Crawford expressing support for Barr Laboratories' application to make Plan B available OTC to women ages 16 and older.

January 21, 2005 The FDA fails to issue a decision on the Plan B application by their own deadline. The Center for Reproductive Rights files a lawsuit on behalf of its Plaintiffs challenging the FDA's failure to approve Plan B for OTC use.

April 6, 2005 Senators Murray (D-WA) and Clinton (D-NY) place a "hold" on Lester Crawford's nomination as Commissioner of the FDA because the FDA had failed to act on the Plan B application and other issues while Crawford served as acting commissioner.

May 12, 2005 Reports surfaces that David Hager, a conservative member of the FDA's Reproductive Health Drug Advisory Committee was asked by an unnamed high-level FDA official to submit a minority opinion in support of his December 2003 vote against OTC status for Plan B.

May 23, 2005 Representative Maloney joins Representative Shays, Slaughter and 51 bipartisan Members of Congress in sending letter to Dara Corrigan, Acting Principal Deputy Inspector General at the Office of Inspector General at the US. Department of Health and Human Services expressing concern and requesting an investigation of the FDA's request for a "minority opinion from Dr. W. David Hager during consideration of Barr Laboratories' application to allow OTC sales of Plan B.

July 15, 2005 Senators Murray and Clinton lift the "hold" on Crawford's nomination in exchange for a promise from Health and Human Services Secretary Mike Leavitt that the FDA would act on the Plan B application by September 1, 2005.

August 26, 2005 Indefinitely deferring a decision, the FDA submits the Plan B application to a 60-day public comment period and an administrative rule making process with no specified deadline regarding the practical implications of approving a dual label product. The FDA changes the age limit to women 17 and older, rather than 16.

August 31, 2005 Susan F. Wood, Ph.D., Assistant Commissioner for Women's Health and Director, Office of Women's Health, resigns in protest over the FDA's handling of the Plan B application.

September 2, 2005 Thirteen senators ask the Government Accountability Office to release its findings from an investigation of the FDA's original denial of application.

September 23, 2005 FDA Commissioner Lester Crawford resigns after only two months as FDA commissioner.

October 7, 2005 Representative Maloney joins 61 bipartisan Members of Congress in sending letter to Acting FDA Commissioner Andrew von Eschenbach, M.D., as part of the FDA's request for public comment on OTC sales of Plan B. The letter expresses disappointment over FDA's decision to delay, postpone, and create impediments to issuing a decision on Plan B and urges FDA to approve Plan B for OTC sales.

October 12, 2005 The Government Accountability Office releases a draft report regarding the Plan B controversy, finding that the decision not to approve Plan B for OTC use was highly unusual, made with atypical involvement from high-level agency officials, and likely was made months before the formal announcement. The final report is slated to be released to the public by early November.

November 1, 2005 FDA 60-day public comment period for administrative rule making process expires.

November 3, 2005 Representatives Maloney, Shays, Inslee, and Crowley introduce "Plan B for Plan B Act of 2005." This bill requires the FDA to finally do its job by making a decision on Plan B– either approving it or denying it.